

7. 510(k) Summary

Submitter Information

- A. Company Name: Baylis Medical Company Inc.
- B. Company Address: 2645 Matheson Blvd. East
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Canada
- C. Company Phone: (905) 602-4875; ext 252
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- E. Contact Person: Meghal Khakhar
- F. Summary Prepared on: June 8, 2010

JUL 28 2010
1K101615

Device Identification

- A. Device Trade Name: PowerWire Radiofrequency Guidewire
- B. Device Common Name: Catheter Guide Wire
- C. Classification Name: Wire, guide, catheter
- D. Device Class: Class II
- E. Device Code: DQX

Identification of Predicate Device

The predicate device is the PowerWire Radiofrequency Guidewire, which is cleared under 510(k) Premarket Notification Number K051670.

Device Description

The present device, PowerWire Radiofrequency Guidewire consists of a core wire surrounded with a polymer insulation. The wire connects to a radiofrequency puncture generator at the proximal end via a connector cable, and has an active tip at the distal end to deliver radiofrequency energy. The changes made to the device include changes in active tip geometry and material and addition of more radiopaque bands.

The PowerWire Radiofrequency Guidewire is designed to be compatible with most balloon and stent catheters approved for use in peripheral interventional procedures.

Indications for Use

The Power Wire Radiofrequency Guidewire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater.

Substantially Equivalent Device

The present PowerWire Radiofrequency Guidewire is substantially equivalent to the currently 510(k) cleared PowerWire Radiofrequency Guidewire (K051670).

Brief Comparison Summary

To demonstrate equivalence of the present PowerWire Radiofrequency Guidewire to the predicate device, technological characteristics and performance criteria were evaluated using testing as listed below.

Using FDA guidance documents and appropriate standards for non-clinical testing of medical devices, the following tests were performed:

- fracture resistance
- damage with repeated flexing
- union strength
- integrity after mechanical shock
- electrical impedance
- high frequency dielectric strength
- mains frequency dielectric withstand
- bending fatigue
- resistance to user manipulation
- proximal stiffness
- distal stiffness
- torqueability
- torque strength
- corrosion resistance
- simulated device use (model bench testing validation)
- cytotoxicity
- sensitization
- irritation (intracutaneous reactivity)
- acute systemic toxicity
- hemocompatibility
- thrombogenicity.

The results from these tests demonstrate that the technological characteristics and performance criteria of the present PowerWire Radiofrequency Guidewire are substantially equivalent to the predicate device for the same intended use.

Conclusion (Statement of Equivalence)

The data and information presented in this application, including non-clinical testing, and the device similarities support a determination of substantial equivalence, and therefore market clearance of the present PowerWire Radiofrequency Guidewire through this Special 510(k) Premarket Notification.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JUL 28 2010

Baylis Medical Company Inc.
c/o Meghal Khakhar, MBBS, CerRAP, RAC
Regulatory Affairs Manager
2645 Matheson Blvd. East
Mississauga, Ontario Canada L4W 5S4

Re: K101615
Trade/Device Name: PowerWire Radiofrequency Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 15, 2010
Received: July 16, 2010

Dear Ms. Khakhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

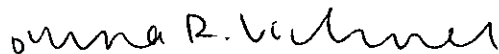
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUL 28 2010

Indications for Use

510(k) Number (if known): K101615

Device Name: PowerWire Radiofrequency Guidewire

Indications For Use:

The Power Wire Radiofrequency Guidewire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Kachner

Division Sign-Off)
Division of Cardiovascular Devices

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